Before the
Federal Communications Commission
Washington, D.C. 20554

In the matter of ANSYS Inc. Request for Waiver of 47 C.F.R. § 1.1307(b)(2) of Commission Rules Declaratory Ruling Concerning Section 1.1307(b)(2) of Commission Rules	)	ET Docket No. 10-166

Order

Adopted: February 1, 2011 **Released: February 1, 2011**

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. This Order grants a waiver to ANSYS Inc. (Ansys) of Sections 1.1307(b)(2) and 2.1093 of the Commission's Rules to permit routine environmental evaluation of medical implant or body-worn equipment authorized for use in the Medical Device Radiocommunication Service (MedRadio) by finite element method (FEM) computational modeling.[1] ANSYS requested a waiver of Section 1.1307(b)(2) to permit the use of FEM-based modeling as an alternative to the finite-difference time-domain (FDTD) technique explicitly permitted by the current rule, and the Commission put its request on Public Notice,[2] receiving a single comment and a single reply comment[3] Both comments support the use of FEM as a sound engineering technique equivalent to the finite-difference time-domain (FDTD) technique explicitly permitted by the current rule.

2. The academic and industry literature supporting the petitioner's assertion that FEM-based modeling is a sound engineering technique supports the conclusion that FEM is a valid analysis technique to demonstrate specific absorption rate (SAR) compliance,[4] when performed using code and model validation protocols and SAR simulation practices as required for FDTD. The petitioner shows good cause for us to grant the request. Particularly, granting the requested relief will reduce costs of development and increase opportunities for innovation and deployment of this valuable service, while maintaining the Commission's high-standard of technical rigor in evaluations of compliance with RF exposure limits. Accordingly, by this Order we grant the instant request for waiver and extend relief to ANSYS and parties using FEM modeling in the routine evaluation of medical implant or body-worn MedRadio equipment. While this waiver acknowledges the evolving industry and academic

[1] Letter from Delbert D. Smith, Counsel to Ansys, Inc. to Ms. Marlene Dortch, Secretary of the Federal Communications Commission, Re: Request for Waiver of 47 C.F.R. § 1.1307(b)(2) (August 2, 2010) ("Request for Waiver" or "Petition").

[2] *Office of Engineering and Technology Declares the ANSYS Inc. Request for Waiver of Rule Section 1.1307 (b)(2) to be a "Permit-But-Disclose" Proceeding For Ex Parte Purposes and Requests Comments*, ET Docket No. 10-166, Public Notice, DA 10-1600 (rel. Aug. 24, 2010) ("Public Notice").

[3] Comments of Cambridge Consultants, Inc., Sept. 21, 2010 ("Cambridge Comments") ANSYS Reply Comment, October 8, 2010.

[4] 47 C.F.R. §§ 1.1307, 2.1093.

recognition of the use of FEM-based modeling and other techniques for the engineering analysis of human exposure to radiofrequency (RF) energy from wireless devices, it applies only with respect to FEM-based modeling and only for MedRadio devices. We thus take only narrow action in the approval of the instant request for waiver, and defer, as appropriate, any broader review of other techniques or methods and use for devices in other services to a future Commission proceeding on RF exposure policy where a full record may be developed.

II. BACKGROUND

3. The Commission has established rules and procedures to protect humans from exposure to potentially harmful levels of RF energy from radio transmitters. The National Environmental Policy Act of 1969 (NEPA) requires agencies of the Federal Government to evaluate the effects of their actions on the quality of the human environment.[5] In response to its NEPA obligation, the Commission, among other things, adopted requirements for evaluating human exposure to RF energy emitted by FCC-regulated transmitters and facilities in ET Docket 93-62.[6] Section 1.1307(b)(2) of the Commission's Rules specifies those mobile and portable devices in certain services that require routine evaluation of human exposure that are, consequently, enforced as part of the Commission's rules and procedures for equipment authorization, administered by the Chief of the Office of Engineering and Technology under authority delegated by the Commission.[7]

4. With respect to MedRadio, Section 1.1307(b)(2) requires demonstration of compliance either by laboratory measurement techniques or by finite difference time domain (FDTD) computational modeling.[8] FDTD is a computational technique used in the scientific and engineering analysis of many electromagnetic wave interactions with material structures, including the analysis of human exposure to RF energy. Our rules permit manufacturers to employ FDTD to predict the potential RF exposure of users to wireless devices. When applied to models of the human anatomy and wireless devices, FDTD can simulate the localized specific absorption rate (SAR) in the human body of users exposed to wireless devices.[9]

5. Other computational modeling techniques, such as FEM, employ different mathematical formulations to model the same fundamental RF energy absorption characteristics and field conditions produced by simulated models of wireless devices and human anatomy.[10] The Institute of Electrical and Electronics Engineers' International Committee on Electromagnetic Safety (IEEE ICES), Technical Committee 34 is currently reviewing FDTD, FEM, finite integration technique (FIT) and other potentially valuable computational techniques for determining SAR to develop standardized methods of application.[11]

6. Similar to our consideration whether FEM may be used under Section 1.1307(b)(2), we also consider particularly whether FEM is satisfactory to meet the requirements of Section 95.1221, which provides that MedRadio equipment be evaluated for radiofrequency radiation exposure compliance in accordance with Sections

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[5] *See* National Environmental Policy Act of 1969, as amended, 42 U.S.C. §§ 4321-4335.

[6] See Report and Order, ET Docket 93-62 (Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation), 11 FCC Rcd 15123 (1996); *Second Memorandum Opinion and Order and Notice of Proposed Rule Making,* ET Docket 93-62, 12 FCC Rcd 13494 (1997); *see also* 47 C.F.R. § 1.1307(b).

[7] *See* 47 C.F.R. § 0.241(b); *see also* 47 C.F.R. § 2.1093(a) (providing that "requirements of this section are a consequence of Commission responsibilities under the National Environmental Policy Act to evaluate the environmental significance of its actions. See subpart I of Part 1 of this chapter, in particular § 1.1307(b).").

[8] 47 C.F.R. § 1.1307(b)(2).

[9] 47 C.F.R. § 2.1093(d).

[10] Cambridge Consultants, in its comment, identifies a difference in the general approach that FDTD and FEM take to analyzing the fundamental RF properties of devices. *See* Cambridge Comments at 2. The Commenter states that FDTD meshes a device's RF emissions with fixed dimension rectangular cells (Yee cells), while FEM uses an unstructured mesh, typically tetrahedral, in calculations of Maxwell's Equations. *See Id.*

[11] *See* Subcommittee 2: Computational Techniques, available at http://www.ices-emfsafety.org/committees_tc34_sc2.php. While the petitioner only seeks review of FEM, we note that finite integration technique is sometimes considered as a variation of the FDTD method, and other possible techniques may also being reviewed in the future by the Committee but are beyond the scope of our review.

1.1307(b)(2) and 2.1093.[12] The Commission's prior decision adopting the rules in Part 95 for MedRadio acknowledged that techniques other than FDTD for evaluating RF exposure for equipment authorization purposes existed, but recognized a lack of sufficient notice on the subject, and deferred full consideration of those issues to a future rulemaking.[13] Nonetheless, the requirements and impacts of Section 95.1221 are similar to those in Section 1.1307(b)(2) so FEM, in addition to FDTD or laboratory measurement techniques, may be used to satisfy the rule requirements in both Sections for routine environmental evaluation of RF exposure necessary for equipment authorization of medical implant or body-worn transmitters.

III. ANSYS PETITION

7. ANSYS Inc. (ANSYS) filed its Request for Waiver of Section 1.1307(b)(2) of the Commission's Rules to allow routine environmental evaluation to be performed by means of FEM computational modeling of radiofrequency (RF) exposure of medical implant or body-worn transmitters authorized for use in the MedRadio Service. ANSYS is the developer and marketer of High Frequency Structure Simulator (HFSS), a FEM-based software tool for simulation of RF fields used by engineers, designers, and researchers in various industries, including RF device manufacturers evaluating potential transmitters RF exposure compliance under Commission rules.

8. In its petition, ANSYS asserts that FEM-based software is capable of simulating the fundamental physics as well as does FDTD-based software, and thus should be permitted for evaluating medical implant or body-worn transmitter compliance with the Commission's RF exposure rules.[14] As part of its petition, ANSYS provides various literature, including peer-reviewed scientific literature, in support of its claim that FEM is recognized and utilized in the industry as a simulation modeling technique of equal merit and credibility to FDTD.[15] ANSYS also asserts that this literature can address what it argues was a deficient record in the original MedRadio proceeding.

9. ANSYS argues that the ongoing work of the IEEE ICES Technical Committee 34 in developing recommended practices for use of both FDTD and FEM for evaluating the RF exposure associated with wireless communication devices further demonstrates that FEM should be considered as an equivalent technique to FDTD.[16] ANSYS asserts no presumption in favor of FDTD's scientific acceptance should be permitted because both FDTD and FEM are still under review by the Technical Committee 34, and neither is currently recognized fully by an IEEE Standard though both are currently under consideration.

10. ANSYS asserts that the literature provided supports a request under Section 1.3 of Commission rules for waiver of Section 1.1307(b)(2) to allow parties to employ FEM-based approaches.[17] ANSYS asserts that its request for waiver is consistent with the requirements of Section 1.925(b)(3), which establishes the basis for evaluating requests for waiver in that (1) the underlying purpose of Section 1.1307(b)(2) would not be served by excluding FEM-based methods and granting the request would be in the public interest; and (2) the unusual circumstances of the exclusion of FEM-based methods from our rules is inequitable, unduly burdensome, contrary to the public interest, and offers no reasonable alternative.[18] It states that the purpose of Section 1.1307(b)(2), to require evaluation prior to equipment approval to safeguard against excessive human exposure to RF emissions, is served by use of FEM, and the availability of additional engineering test methodologies.[19] ANSYS argues that

[12] 47 C.F.R. § 95.1221 (providing that radiofrequency radiation exposure compliance be evaluated in accordance with Sections §§ 1.1307 and 2.1093 of Commission rules).

[13] *See*, "Investigation of the Spectrum Requirements for Advanced Medical Technologies Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz" *Report and Order* in ET Docket No. 06-135, RM-11271, ("MedRadio R&O") 24 FCC Rcd 3474, 3493.

[14] *See* Petition at 2-3.

[15] *See* Petition Attachment B.

[16] *See* Petition at 3.

[17] *See Id.*; *see also* 47 C.F.R. § 1.3.

[18] *See* 47 C.F.R. § 1.925(b)(3).

[19] *See* Petition at 3.

approval of its request for waiver is in the public interest, and would, among other things, provide manufacturers and researchers with new and alternative SAR computational methodologies for MedRadio devices, thus lowering the costs of product development. ANSYS also asserts that approval of its request would rectify inequitable treatment of ANSYS and potential users of FEM-based techniques, and provide a more technology neutral basis for Section 1.1307(b)(2).

IV. COMMENTS

11. The Commission sought comment on the ANSYS petition for waiver in a Public Notice released Aug. 24, 2010.[20] One comment from Cambridge Consultants Inc. supporting the request and a reply by ANSYS were received in response.[21] Cambridge Consultants utilizes ANSYS' FEM-based modeling software for use in engineering consulting work designing antenna systems for implantable devices operating under the MedRadio service rules at issue in this review.[22] It requests that the Commission approve the ANSYS request for waiver because it is in the public interest. Cambridge Consultants also provides support based on its own work with FEM-based modeling as well additional references to additional scientific literature. In general, Cambridge Consultants acknowledges that differences between FDTD and FEM do exist, and it submits that while a single FDTD simulation can provide data over a wide frequency range, a FEM simulation is limited to a particular frequency. At the same time, it observes that RF implants are constrained to operate within a single frequency band under the MedRadio rules so FEM-based modeling would result in no loss of generality over FDTD.[23] Cambridge Consultants accordingly supports ANSYS' assertion that the results for the two simulation methods are nearly identical.[24]

12. Cambridge Consultants asserts that in situations where computational resources are not an issue, both FDTD and FEM-based methods yield equivalent results, making either method equivalent for evaluating RF exposure.[25] No parties commented that lack of adequate computational resources constrain use of either technique, and we do not believe that computational resources offer any practical restrictions on the choice of a particular computational technique The Commenter also asserts that FEM techniques permit use of an unstructured mesh, which offers an advantage over FDTD in the testing of implant devices because FEM-based models conform to curved surfaces (such as the organs within the human body) better than FDTD models,[26] and argues that FEM modeling, by virtue of its unstructured mesh, may therefore constitute a better modeling approach than FDTD for the particular conditions of implant testing. ANSYS filed a reply comment on October 8, 2010 referencing the Comment of Cambridge Consultants and other references filed in response to their petition, and urged the Commission to approve their request for waiver.[27]

V. DECISION

13. As noted above, the proceeding in which we adopted the rules establishing that FDTD-based computational modeling be used to model the SAR of MedRadio devices did not inquire as to the propriety of using FEM-based computational models as an alternative, and thus did not give sufficient notice to consider that issue.[28] In support of the instant petition, ANSYS and Cambridge Consultants have here presented scientific evidence in support of the use of FEM-based methods in the instant request for waiver, from diverse sources, including peer-

[20] *See* Public Notice (declaring this proceeding a "permit-but-disclose" proceeding for *ex parte* purposes).

[21] *See generally* Cambridge Comments; *see also* Reply Comments of ANSYS, Inc., October 8, 2010.

[22] *See* Cambridge Comments at 1.

[23] *See Id*. at 2-3.

[24] *See Id*. at 1-2.

[25] *See Id*. at 2.

[26] *See Id*. at 2-3.

[27] ANSYS Reply Comment (October 8, 2010).

[28] *See* MedRadio R&O,*supra* at 3493. The Commission did not reject FEM-based computational modeling, but simply did not consider it at that time. *Id.*

reviewed scientific journals, and demonstrates that both FEM-based and FDTD-based methods can produce equivalent results in the computation of SAR values. Moreover, the comments of Cambridge Consultants suggest that FEM-based modeling may offer some benefits over FDTD approaches for evaluation of the implant devices at issue here. When the Commission reviewed these issues in the MedRadio proceeding, FDTD-based methods were already widely used for the modeling of SAR. , but tThe information provided in the record here now demonstrates that FEM-based approaches to modeling SAR values are also mature. ANSYS' assertion regarding the technical equivalence and lack of sound engineering basis for excluding FEM-based methods for use in computing SAR is likewise supported by the comments and evidence from engineering sources referenced in the request for waiver.

14. We find that the ANSYS request satisfies the requirements of Section 1.925(b)(3) for a waiver of Commission rules. While ANSYS' request for waiver of Section 1.1307(b)(2) could be granted to permit ANSYS as a responsible party to use FEM-based models to satisfy the requirements of Section 1.1307(b)(2), we believe the appropriate scope of the request is implicitly broader and should be extended to any party using FEM methods to satisfy the requirements of the rules for environmental evaluation of MedRadio equipment, such as the commenting party Cambridge Consultants. Accordingly, the relief granted here will allow any party to satisfy the requirements of 1.307(b)(2) and certify MedRadio devices using FEM-based techniques, including those of ANSYS' HFSS.

15. The literature presented by the petitioner and commenting party establish a sound engineering record for our determination that FEM-based models are an equivalent engineering alternative to use of FDTD approaches. This peer-reviewed literature demonstrates that the FEM-based calculations agree with FDTD calculations as used at many laboratories, and that differences among FDTD results can exist.[29] Further, peer-reviewed literature also shows that comparison of measured magnetic fields with fields calculated using the FEM technique show good agreement.[30] The evidence presented indicates that allowing the use of FEM-based approaches would not compromise or weaken the technical rigor of the compliance testing required, and to the contrary could offer certain benefits to the quality of evaluations presented to the Commission.

16. Therefore, we believe that granting ANSYS' request for waiver it is appropriate and, *sua sponte*, extend this relief to other parties seeking to employ FEM-based modeling approaches in the evaluation of MedRadio implant devices as required by Sections 1.1307(b)(2), 2.1093 and 95.1221 of Commission rules.[31] Subject to a party's use of the same code and model validation protocols and SAR simulation practices as required for FDTD, parties may employ FEM-based computational modeling in the routine environmental evaluation for RF exposure prior to equipment authorization for equipment used as a medical implant or body-worn transmitter as defined under Subpart E of Part 95.

17. This relief will further the public interest by allowing innovators additional flexibility in seeking equipment authorizations supporting compliance with the SAR limits in Section 2.1093(d) for MedRadio Service transmitters using FEM-based methods. We recognize that other numerical methods could also be shown to be equivalent to the FDTD and FEM implementations. For example, industry practice suggests that FIT is sometimes considered as a variation of the FDTD method, but such other approaches are neither before us nor supported by this petition and the record before us. We also note that the Commission stated that action on these broader issues had implications beyond the specific context of MedRadio devices and that a comprehensive decision on the matter should be supported in a separate rulemaking on RF safety issues.[32] We do not address the broader concerns of acceptability of other computational methods or the removal of specific references to any particular method in our rules. This decision only responds to ANSYS' specific request for waiver of the rules with respect to MedRadio devices and the use of the FEM-based modeling approach. This decision does not change or relax our underlying rules limiting human exposure to radio frequency energy. The decision remains otherwise untouched our established equipment authorization and RF exposure standards and procedures, and defers any broader issues to a future proceeding appropriate for developing a full record on the general use of computer models in demonstrating

[29] Siegbahn, Martin, *et al*, "An International Interlaboratory Comparison of Mobile Phone SAR Calculation with CAD-Based Models," IEEE Trans on EMC, Vol. 52, No. 4, Nov. 2010.

[30] Šimunić, Dina, *et al*., "Spatial Distribution of High-Frequeny Electromagnetic Energy in Human Head Druing MRI: Numerical Results and Measurements," IEEE Trans Biomed Eng, Vol. 43, No. 1, Jan 1996.

[31] *See* 47 C.F.R. §§ 1.1307(b)(2), 2.1093 and 95.1221.

[32] *See* MedRadio R&O, at 3493 paras. 68.

compliance with the Commission's RF exposure limits.

VI. ORDERING CLAUSES

18. Accordingly, **IT IS ORDERED** that the petitioner's request IS GRANTED with respect to the request for waiver, to the extent discussed above, pursuant to authority delegated by Section 0.241(b) of the Commission's rules, so that the use of FEM-based computational models for environmental evaluation of MedRadio equipment may be used to satisfy the requirements of Sections 1.1307(b)(2), 2.1093, and 95.1221 of Commission rules (47 C.F.R §§ 1.1307(b)(2), 2.1903, 95.1221).[33]

19. **IT IS FURTHER ORDERED** that this order is effective upon adoption; petitions for reconsideration under Section 1.106 of the Commission's rules (47 C.F.R. § 1.106) may be filed within 30 days of the date of the release of this Order.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp
Chief
Office of Engineering and Technology

[33] *Id.*.